REMARKS

The rejection of claims 1-4, 7-18, 23, 24, 35, 36, 38-41 and 43-47 was made final in an action mailed October 18, 2005. In this submission being made in connection with a request for continued examination, Applicants have amended pending independent claims 1, 10, 35 and 40, as well as pending dependent claims 3-4, 7-8, 14-16, 36, 39, 41 and 43, and have canceled claims 2 and 12-13. Claims 25-34 had been canceled in a prior amendment. Claims 5-6, 19-22, 37 and 42 were withdrawn in a prior amendment in response to an election of species requirement. Accordingly, claims 1, 4-11, 14-24, 35-47 are pending, but of those claims, 5-6, 19-22, 37, and 42 are presently withdrawn from consideration.

In view of the amendments to the claims and the following remarks, Applicant requests favorable consideration of claims 1, 4, 7-11, 14-18, 23-24, 35-36, 38-41 and 43-47; and asks that the Examiner consider, pursuant to 37 C.F.R. 1.141, the patentability of withdrawn claims 5-6, 19-22, 37 and 42 as being in dependent form and including all the limitations of an allowed generic claim. Applicant also asks that the Examiner review the reference submitted in the Supplemental Information Disclosure Statement being filed on even date with the present request for continued examination.

Claim Amendments

To advance prosecution, Applicant has amended each of the pending independent device claims 1 and 10 and pending independent method claims 35 and 40 to distinguish further the cited references upon which the examiner relies, and has amended various dependent claims for consistency. These amendments add no new matter.

Independent device claims 1 and 10 and their dependent claims

Independent claim 1 stands rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2004/0215177 to Swanson. All of the claims that depend either directly or indirectly from claim 1 also stand rejected either under Section 102(e) as anticipated by Swanson or under Section 103(a) as obvious in view of Swanson in view of U.S.

Patent 5,799,661 to Boyd et al. Independent claim 10, and all of its dependent claims, stand rejected under Section 103(a) as obvious in view of Swanson in view of Boyd et al. Applicant submits that claims 1 and 10, as amended, each defines subject matter that is patentable over the references of record.

Swanson, which is commonly assigned to the assignee of the present application, is directed to apparatus and methods for insulating tissue during therapeutic procedures such as cryogenic cooling. (Abstract and Para. 0005.) Swanson describes that, during cryogenic cooling of body tissue, tissue is contacted with a cryogenic element, such as a balloon or hollow metal tip, and is cooled to a temperature the causes tissue death. (Para. 0005.) Swanson discloses that the catheter-based probes used to create lesions (i.e., cause tissue death) typically include a relatively long and flexible catheter body that supports a cryogenic element at or near its distal end. (Para. 0040.) Swanson further discloses that the portion of the catheter body that is inserted into the patient is typically from 60 to 140 cm in length, and that there may be another 20 to 40 cm, including a handle, outside the patient. (Para. 0040.) Swanson discloses that the length and flexibility of the catheter body allow the catheter to be inserted into a main vein or artery (typically the femoral vein) and directed into the interior of the heart such that the cryogenic element contacts the tissue that is to be ablated. (Para. 0040.)

Boyd et al. discloses devices and methods for performing port-access or closed-chest coronary artery bypass surgery, including a topical hypothermia device for use during a port-access bypass procedure. The topical hypothermia device has a flexible heat exchanger that is collapsible into a pre-deployed position to fit through an access port made in the chest of the patient. According to Boyd et al., the topical hypothermia device has a short tubular shaft made of rigid material, such as stainless steel or a hard plastic. The outer sheath of the device (Fig. 42, #239) is sized to fit through an access cannula with a 10-12 mm internal diameter. Because the Boyd et al. device is intended to pass through a short access cannula, the device is short, has a rigid shaft, and a relatively large outer diameter.

Neither reference discloses a medical device as set forth in either independent claim 1 or independent claim 10. Swanson, for example, does not disclose, as required by each of claims 1

and 10, a device with a tissue cooling structure affixed to a distal end of an elongate shaft, which tissue cooling structure is deployable by moving the elongate shaft distally relative to an elongate sleeve to advance the tissue cooling structure from a retracted position within the elongate sleeve to a deployed position that extends from a distal end of the elongate sleeve. Swanson, by contrast, discloses a catheter-type device with a distal tissue ablating structure (a balloon or a hollow metal tip). While the balloon of Swanson may be expandable, the distal tissue ablating structure of Swanson is not deployable as specified in claims 1 and 10, namely, by moving the elongate shaft distally relative to an elongate sleeve to advance the tissue cooling structure from a retracted position within the elongate sleeve to a deployed position that extends from a distal end of the elongate sleeve.

Boyd et al., for example, does not disclose, as required by each of independent claims 1 and 10, a medical device comprising an elongate sleeve having a distal end that is sized and adapted to enter into a body blood vessel. Indeed, the distal end of the Boyd et al. device is not sized and adapted to enter into a body blood vessel, as discussed above.

It would also not have been obvious to one of skill in the art to combine the teachings of Boyd et al. with Swanson. The Boyd et al. pad is not, as the examiner contends, an obvious alternative to the cooling used by Swanson (see Response to Arguments section of Examiner's Action of March 3, 2006). Indeed, Swanson and Boyd et al. are directed to entirely different fields of use. Swanson discloses ablation catheters that are intended to ablate or kill body tissue by freezing the tissue, whereas Boyd et al. provides a structure that is adapted to cool but not ablate tissue. As such, one of skill in the art would not look to the Boyd et al. structure as a design alternative to the tissue ablating structures described Swanson. Rather, one of skill in the art would look to structures known to be useful in tissue ablation. There is no suggestion in any reference to make any such design change, and the examiner has not identified any such suggestion in a reference, as the examiner is required to do to meet his burden in support of an obviousness rejection.

In addition, the device of claim 1 is a new structure that is optimally suited for an important new application of cooling tissue within a heart chamber when blood flow to the heart

chamber is temporarily reduced or entirely blocked (so as to reduce reperfusion injury after normal blood flow resumes), which is an application that is not even contemplated by Boyd et al. or Swanson. For example, as described in Applicant's specification at page 10, line 19, through page 12, line 25, Applicant's device has an elongate sleeve with a distal end suitable for entry into a body blood vessel and positionable, for example, within a heart chamber. Once positioned, the deployable structure may be longitudinally deployed from a distal end of the elongate sleeve to cool a target tissue region within the heart chamber.

As such, the claimed device permits the targeted cooling, by direct contact, of tissue located inside a heart chamber. By contrast, the Boyd et al. device does not cool target tissue regions accessed via body blood vessels, but rather has a structure that cools the outside of the heart through an invasive procedure that requires the formation of a hole in the patient's chest. In addition, the size and structure of the Boyd et al. device is suitable for topical cooling applications and does not even suggest a structure that may be used for internal cooling of vessels and organs, such as cooling tissue inside a heart chamber. Due to the structural constraints of Boyd et al., one of skill in the art would not look to Boyd et al. for cooling where access via body blood vessels is required.

Accordingly, Applicant requests that the Examiner remove the standing rejections of independent claims 1 and 10, as well as the rejections of corresponding dependent claims 4, 8-9, 14-18, 23-24 and 44-45.

Independent method claims 35 and 40 and their dependents

Independent method claims 35 and 40 each stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2004/0215177 to Swanson. All of the claims that depend either directly or indirectly from claims 35 and 40 also stand rejected either under Section 102(e) as anticipated by Swanson or under Section 103(a) as obvious in view of Swanson in view of U.S. Patent 5,799,661 to Boyd et al.

The methods set forth in claims 35 and 40 require the introduction into a body vessel of a catheter having an elongate sleeve and an inner shaft having a tissue cooling structure affixed to

a distal end of the elongate shaft, and requires that the inner shaft be moved distally relative to the elongate sleeve to deploy the tissue cooling structure from the distal end of the elongate sleeve. For the reasons discussed above in connection with claim 1, such a structure and its use to treat tissue accessible by a body vessel is not described in either Swanson or Boyd et al. As previously discussed, the catheter used in the methods of claims 35 and 40 is a new structure that is optimally suited for an important new application of cooling tissue, for example within a heart chamber, when blood flow to the heart chamber is temporarily reduced or entirely blocked (so as to reduce reperfusion injury after normal blood flow resumes). This is an application that is not even contemplated by any prior art reference at issue.

In addition to the structural differences of the device used in method claims 35 and 40, neither Swanson nor Boyd et al. discloses a method that involves the use of a catheter introduced through a body vessel to a tissue site to cool, but not ablate, body tissue, as is required by each of independent claims 35 and 40, as amended. As discussed previously, the catheters disclosed in Swanson by contrast, while capable of being introduced through a body vessel, are used specifically for tissue ablation. In addition, Boyd et al., by contrast, does not disclose or suggest the use of a cooling device that is introduced into a body vessel to reach a target tissue area, and is not adapted to be used in that manner either. Indeed, the heat exchanger of the hypothermia device disclosed in Boyd et al. is intended for topical cooling of the entire tissue region on the underside of the heart (i.e., the outside surface of the heart), and is too large to be deployed inside the body. As such, only with the benefit of hindsight could it be said it would be obvious to combine two different references (namely, Swanson and Boyd et al.) to render obvious Applicant's claimed method when, indeed, neither reference contemplates the methods that are the subject of Applicant's claims 35 and 40.

Furthermore, independent method claim 40 specifically requires that the target tissue region that is cooled, but not ablated, be within a chamber of the heart. Again, neither Swanson nor Boyd et al. discloses cooling tissue within a chamber of the heart without ablation.

Accordingly, Applicant requests that the Examiner remove the standing rejections of independent claims 35 and 40, as well as the rejections of corresponding dependent claims 36, 38-39, 41, 43 and 46-47.

Request for Consideration of Non-Elected (Withdrawn) Dependent Claims

Pursuant to 37 CFR 1.142(b), the Examiner withdrew claims 5-6, 19-22, 37, and 42 from consideration as being drawn to a non-elected invention. Claims 5-6 depend from claim 1, claims 19-22 depend either directly or indirectly from claim 10, claim 37 depends from claim 35, and claim 42 depends from claim 40. Because independent claims 1, 10, 35, and 40 are each generic and allowable, and the claims that depend from these generic claims including all of the limitations of the generic claims, Applicant contends that dependent claims 5-6, 19-22, 37, and 42 are entitled to consideration and allowance pursuant to 37 CFR 1.141. Accordingly, Applicant asks that the Examiner consider these claims.

CONCLUSION

Applicant submits that all pending claims 1, 4-11, 14-24, 35-47 are in condition for allowance and respectfully requests that the Examiner issue a notice of allowance. In addition, Applicant asks that the Examiner consider references cited in a supplemental information disclosure statement filed September 5, 2006.

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Please apply the required RCE fee of $790.00 and any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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